FEB – 4 2010

510(k) SUMMARY K092800

LED Intellectual Properties, LLC

Device: Anti-Wrinkle Light, Model AAL

1. General Information

Date Prepared: September 8th, 2008

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On Behalf of: LED Intellectual Properties, LLC
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2. Names and Code

Device Proprietary Name: Anti-Wrinkle Light, Model AAL

Classification Name: Laser Instrument for General and Plastic Surgery

Classification Code: ONE, Class II

3. Predicate Devices

Omnilux New-U (K062991)
Light BioScience Gentlewaves Consumer LED (K072459)
Omnilux Revive & Plus Combo (K050216)
Emergo Group LumiPhase-R (K051255)

4. Device Description

The Anti-Wrinkle Light, Model AAL is a hand-held device consisting of low intensity light emitting diodes (LED's) that emit Low and Sub- IR light for direct exposure to the skin. The device components include an LED array of 605nm, 630nm, 660nm, and 855nm wavelengths, a (non-flammable

plastic) hand piece housing a printed circuit board upon which the LED's are mounted, single non-timer on/off switch with 5-ohm resistor, receiver jack in the hand piece accommodating a removable power cord and a separate AC to DC (9-volt) power supply. Treatment time is recommended to be 3 minutes and is controlled by the user.

5. Substantial Equivalency- Device Comparison Table (Also attached Excel)

		Predicate	Predicate	Predicate	Predicate
Device:	Anti-Wrinkle Light	New-U	Revive&Plus Combo	GentlewavesConsumr	LumiPaseR
Company:	LED Intellecual	PhotoTherpeutic	Photo Therapeutics	LightBioScience	Emergo Group
FDA K#:	K092800	K072459	K050216	K072459	K051255
Indication For Use:	**Same**	Same	Same	Same	Same
	Intended for Over-The-Counter use for the reduction of periobital wrinkles and rhytides.				
Power:	AC to DC	AC to DC	110 volt AC	AC to DC	110 volt AC
Wavelength:	605,630, 660,855nm	633,830nm	633, 830nm	590nm	660nm
Target size:	4sq in	4sq in	Approx. 150sq in	2-4sq in	Approx. 150sq in

6. Biocompatibility

The sections of the device that come in contact with the user are the HIPS plastic handle and glass polymer LED's, which are non-sterile and are the same materials as employed on predicate devices.

7. Indications for Use / Intended Use

The Anti-Wrinkle Light, model: AAL, is a handheld device intended for use in the treatment of periorbital wrinkles.

8. Performance Data

After an analysis of the safety, indications and intended uses, performance, features, technological properties and methods of operation, LED Intellectual Properties, LLC believes that no significant differences exist between the predicate devices listed in Section 3, above. A clinical study has been submitted.

We request substantially equivalency.

9. Additional Information

Individual subjects participating in the clinical study treated only under-the-eye and corner-of-the-eye regions, as shown in the current operator manual

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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LED Intellectual Properties, LLC
% AEGIS Regulatory, Inc.
Mr. Robert T. Wagner
1131 Anthem View Lane
Knoxville, Tennessee 37922

Re: K092800
Trade/Device Name: Anti-Wrinkle Light, Model AAL
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and Plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONE
Dated: February 01, 2010
Received: February 02, 2010

Dear Mr. Wagner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: KO92800

Device Name: LED Intellectual Properties, LLC – Anti-Wrinkle Light model: AAL

Indications For Use:

The Anti-Wrinkle Light is a hand held device intended to emit energy in the visible and IR regions of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) for NRC 2/4/10

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092800